

Remarks

I. Support for Amendments

Support for the foregoing amendments to the claims may be found throughout the specification as originally filed, either inherently or explicitly. Hence, the foregoing amendments to the claims do not add new matter, and their entry and consideration are respectfully requested.

II. Status of the Claims

Upon entry of the foregoing amendments, claims 14-20, 27 and 32-57 are pending in the application, with claims 14, 16 and 44 being the independent claims. Claims 14 and 56 are currently amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

III. Summary of the Office Action

In the Office Action dated October 27, 2004, the Examiner has objected to claim 14, and has made three rejections of the claims. All objections and rejections that were not reiterated from the previous Office Action dated March 24, 2004, were withdrawn. Applicants respectfully offer the following remarks to accommodate or traverse each of the outstanding objections and rejections in the Office Action.

IV. Withdrawal of Claims 40-43 and 52-55

At page 2, section 1 of the Office Action, the Examiner stated that claims 40-43 and 52-55 were withdrawn due to restriction requirement. Applicants respectfully assert that this is incorrect: these claims were withdrawn due to an *election of species* requirement, not a restriction requirement. As such, Applicants respectfully remind the Examiner of their entitlement to consideration of claims to additional species in the event that a generic claim is found to be allowable in accordance with 37 C.F.R. §1.141.

V. Objections to the Claims

The Examiner has objected to claim 14 for an alleged informality because the claim recites "one or more integration sequence-containing nucleic molecules." Office Action at page 2, section 2. Solely in an effort to facilitate prosecution, and without narrowing the scope of the claim, Applicants have amended claim 14 to recite "one or more integration sequence-containing nucleic acid molecules," as suggested by the Examiner.

Hence, the objection to the claims has been rendered moot or otherwise addressed by Applicants' amendments and/or remarks, and Applicants respectfully request that the objection to the claims be reconsidered and withdrawn.

VI. The Rejections under 35 U.S.C. § 112, Second Paragraph

In the Office Action at pages 2-3, sections 3-5, the Examiner has rejected claim 56 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse this rejection.

In particular, the Examiner has asserted that:

Claim 56 recites the limitation "said second nucleic acid comprising said transferred first segment" in the claim. There is insufficient antecedent basis for this limitation in the claim since claim 44 describes that "transferring said first segment from said first nucleic acid molecule to said second nucleic acid molecule" and the second nucleic acid recited in step (b) of claim 44 does not have said transferred first segment.

Office Action at page 3. Applicants respectfully disagree with the Examiner's assertions.

Applicants believe that the claim as originally filed, when read in light of the specification, would reasonably apprise one skilled in the art of the metes and bounds of the claimed invention. Nevertheless, without narrowing the scope of the claim, Applicants have amended claim 56 to recite: "selecting for the second nucleic acid molecule of (c)," thereby making explicit that which was at least implicit. Part (c) of claim 44 recites "transferring said first segment from said first nucleic acid molecule to said second nucleic acid molecule." Thus, the further part (d) recited in amended claim 56 makes clear that the second nucleic acid molecule that is being selected for is the second nucleic acid molecule of part (c), such that the second nucleic acid molecule comprises the transferred first segment.

The Examiner's grounds of rejection of claim 56 under 35 U.S.C. § 112, second paragraph, have been addressed by Applicants, and it is believed that this rejection has been fully accommodated. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are therefore respectfully requested.

VII. *The Rejection of Claims 14-20, 27, 32, 33, 44-46, and 57 under 35 U.S.C. § 102(b) Over Stemmer is Traversed*

The Examiner has maintained the rejection of claims 14-20, 27, 32, 33, 44-46 and 57 under 35 U.S.C. § 102(b), for allegedly being anticipated by Stemmer (U.S. Patent No. 5,605,793; Doc. AB3, of record; hereinafter "Stemmer"). Office Action at pages 3-10, section 7. Applicants respectfully traverse this rejection.

The Examiner repeated the arguments set forth in the Office Action dated March 24, 2004, and further asserted that Applicants' arguments in the Reply filed June 23, 2004, were not persuasive. Specifically, the Examiner asserted that "the ligase taught by Stemmer is a recombination protein." Office Action at p. 10, section 7.

Applicants respectfully disagree with the Examiner's assertions for the reasons set forth in the Reply filed June 23, 2004, and for the following reasons. The Examiner cited *In re Van Geuns* for the proposition that "[a]lthough the claims are interpreted in light of the specification, limitations from the specification are not read into the claims." Office Action at page 10, citing *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). However, *Van Geuns* is distinguishable from the present case. In *Van Geuns*, the senior party to an interference attempted to distinguish a prior art reference that rendered obvious one of the claims at issue by arguing that the phrase "uniform magnetic field" must be interpreted in light of the specification and understanding of persons skilled in the NMR and MRI art because the reference did not teach the level of magnetic field uniformity required for NMR imaging. However, the claim at issue was not expressly limited to NMR or MRI, so the Federal Circuit refused to read those limitations into the claim. Importantly, there is no indication in *Van Geuns* that the

specification explicitly defined "uniform magnetic field" to be only in the context of NMR or MRI applications.

In contrast, the present specification does define a "recombination protein":

Site-specific recombinases are proteins that are present in many organisms (e.g. viruses and bacteria) and have been characterized as having *both endonuclease and ligase properties*. These recombinases (along with associated proteins in some cases) recognize specific sequences of bases in DNA and *exchange the DNA segments* flanking those segments. *The recombinases and associated proteins are collectively referred to as "recombination proteins" (see, e.g., Landy, A., Current Opinion in Biotechnology 3:699-707 (1993)).*

Specification at page 2, lines 3-9 (emphasis added). *See also*, Specification page 25, line 22 to page 26, line 11 and page 29, lines 12-22.

It is well established that, "[w]here an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. M.P.E.P. § 2111.01 III (Rev. 2, May 2004) (citing *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999)). Thus, a recombination protein, as that term is defined and used in the present specification and claims, must have both endonuclease and ligase properties and exchange DNA segments. The Examiner, however, has selectively chosen phrases from the specification to fashion his own definition of "recombination protein" as "proteins that are involved in recombination reactions involving one or more recombination sites," apparently ignoring part of the definition. *See* Office Action at page 4. Applicants respectfully submit that this is improper. Nevertheless, even using the Examiner's selective definition, "recombination protein" must have endonuclease and ligase properties and exchange DNA segments because the recombination proteins "are

involved in recombination reactions involving one or more recombination sites."

Recombination sites are defined in the present specification as "discrete sections or segments of nucleic acid on the participating nucleic acid molecules that are recognized and bound by a site-specific recombination protein during the initial stages of integration or recombination." Specification at page 25, line 28 to page 26, line 3. In turn, the recombination proteins which recognize recombination sites *have endonuclease and ligase properties, and exchange DNA segments. See* Specification at page 2, lines 3-9 and page 29, lines 12-22. Hence, a "recombination protein" as that term is defined and used in the present specification and claims, has both endonuclease and ligase properties, and exchanges DNA segments.

As one of ordinary skill in the art would be well aware, the ligase enzyme disclosed in Stemmer does not have endonuclease activity. Hence, the Stemmer ligase does not "have both endonuclease and ligase properties" and does not "exchange DNA segments," and therefore, is distinguishable from the recombination proteins involved in the methods of the presently claimed invention. Since the Stemmer ligase does not possess all of these properties, by definition it cannot be a "recombination protein." That is not to say that ligases of the sort disclosed in Stemmer could not be used in conjunction with the present invention. The point here is simply that the ligases described in Stemmer cannot be considered as recombination proteins as that term is defined and used in the present specification and claims.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026

(1984). As noted above, Stemmer does not expressly or inherently disclose the presently claimed methods. Hence, under *Kalman*, this reference cannot and does not anticipate the claims as currently presented.

In view of the foregoing remarks, reconsideration and withdrawal of the rejection of claims 14-20, 27, 32, 33, 44-46 and 57 under 35 U.S.C. § 102(b) over Stemmer are respectfully requested.

VIII. The Rejection of Claims 14-20, 27, 32, 33, 44-46, and 57 under 35 U.S.C. § 102(b) Over Atlung et al. is Traversed

The Examiner has also maintained the rejection of claims 14-20, 27, 32, 33, 44-46, and 57 under 35 U.S.C. § 102(b), for allegedly being anticipated under 35 U.S.C. § 102(b) by Atlung *et al.*, *Gene* 107: 11-17 (1991) (Doc. AT4, of record; hereinafter "Atlung"). See Office Action at pages 10-17, section 8. Applicants respectfully traverse this rejection.

The Examiner repeated the arguments set forth in the Office Action dated March 24, 2004, and further asserted that Applicants' arguments in the Reply filed June 23, 2004, were not persuasive. Specifically, the Examiner asserted that:

"integration sequence" is defined as "any nucleotide sequence that is capable of inserting randomly into a target nucleic acid molecule" (see the specification, page 22, last paragraph bridging to page 23, first paragraph.) Since purified BstE II-Xho I fragment of pTAC3599 carrying the *phoA* gene and the *appYp-lacZ* fusion taught by Atlung *et al.*, is considered as an integration sequence in the rejection and applicant does not provide an [sic] evidence to show why purified BstE II-Xho I fragment of pTAC3599 carrying the *phoA* gene and the *appYp-lacZ* fusion can not be inserted randomly into a target nucleic acid molecule, Atlung *et al.*, do teach integration sequences. Furthermore, it is known that a DNA can be randomly inserted in the genome of a cell if the DNA is microinjected into the cell.

Office Action at page 16. Applicants respectfully disagree with the Examiner's assertions.

As noted above, a claim can only be anticipated under 35 U.S.C. § 102 if every element in the claim is expressly or inherently disclosed in a single reference. *See Kalman*, 713 F.2d at 771. Applicants respectfully maintain that Atlung does not disclose all of the elements of independent claims 14, 16 and/or 44 (and, hence, of the claims that depend directly or indirectly therefrom), as set forth in detail in Applicants' Reply filed June 23, 2004. In particular, Applicants maintain that Atlung does not disclose "integration sequences" as that term is used in the present specification and claims. Specifically, the present specification defines an "integration sequence" as "any nucleotide sequence that is capable of inserting randomly into a target nucleic acid molecule." Specification at page 22, line 29 to page 23, line 2. In contrast, Atlung discloses the use of *traditional cloning methods to ligate* a nucleic acid fragment that has been digested with restriction enzymes into a *specific* location in a plasmid that has *compatible ligation ends*. Thus, Atlung simply does not describe a nucleotide sequence capable of *random insertion* into a target nucleic acid molecule, and therefore does not describe integration sequences as that term is described and used in the present specification and claims.

Not only does Atlung does not expressly describe integration sequences as that term is defined and used in the present specification and claims, the Examiner also has not shown that such integration sequences are inherently described therein in order to meet the burden of showing anticipation under 35 U.S.C. § 102(b). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning

to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112 IV (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). In the present case, the Examiner has merely made an unsupported assertion that "it is known that a DNA can be randomly inserted in the genome of a cell if the DNA is microinjected into the cell." Office Action at page 16. Besides being completely irrelevant to the patentability of the present claims, this unsubstantiated allegation is not a sufficient basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic of random insertion necessarily flows from Atlung. In fact, even assuming, *arguendo*, that a DNA fragment microinjected into a cell *could* randomly insert into a genome, it is still an irrelevant point: Atlung says absolutely nothing about microinjecting the BstE II-Xho I fragment--or any other nucleic acid, for that matter--into a cell. Moreover, the mere fact that a DNA fragment microinjected into a cell *can* randomly insert into the cell's genome does not guarantee that it *will* happen. It is at least equally likely that when a DNA molecule is microinjected into a cell that it is not incorporated into the host cell genome, particularly if the host cell is a bacterium, where it is more likely that the microinjected DNA remains extra-genomic. Thus, the Examiner has not shown how the concept of microinjection of a DNA fragment is established from Atlung, nor that random insertion of DNA into a genome necessarily flows from the act of microinjecting DNA into a host cell. Thus, Atlung does not inherently teach the integration sequences as that term is defined and used in the present specification and claims.

The Examiner further asserted that ligation sites as described in Atlung can be considered as "recombination sites." Office Action at page 17. Applicants respectfully disagree with the Examiner's assertion and respectfully maintain that, for the reasons set forth in the previous reply filed June 23, 2004, the ligation sites disclosed in Atlung are not recombination sites as that term is defined and used in the present specification and claims. Specifically, the present specification makes quite clear that standard ligation sites (*i.e.*, sites at which nucleic acid molecules are to be joined by ligase enzymes in traditional restriction cloning methods) are *not* considered recombination sites in accordance with the present invention:

Site-specific recombinases are proteins that are present in many organisms (e.g. viruses and bacteria) and have been characterized as having both endonuclease and ligase properties. These recombinases (along with associated proteins in some cases) recognize specific sequences of bases in DNA and exchange the DNA segments flanking those segments. The recombinases and associated proteins are collectively referred to as "recombination proteins" (*see, e.g.*, Landy, A., *Current Opinion in Biotechnology* 3:699-707 (1993)).

* * *

A key feature of the recombination reactions mediated by the above-noted recombination proteins are recognition sequences, often termed "recombination sites," on the DNA molecules participating in the recombination reactions. These recombination sites are discrete sections or segments of DNA on the participating nucleic acid molecules that are recognized and bound by the recombination proteins during recombination.

Specification at page 2, lines 3-9, and page 4, lines 15-20. Hence, ligation sites (or, more accurately, restriction sites) do not qualify as "recombination sites," since the ligase enzyme that binds ligation sites (or the restriction enzyme that cleaves at restriction sites) does not "have both endonuclease and ligase properties" and does not "exchange DNA segments." Since the Atlung ligation sites are associated with a liagse, which, as set

forth in the preceding section with respect to Stemmer, is not a recombination protein, the Atlung ligation sites are not recombination sites.

This is not to say, of course, that ligation sites cannot comprise one or more recombination sites, or that recombination sites as defined in accordance with the present invention cannot be located at or near the termini of linear or nicked circular nucleic acid molecules. The point here is simply that the restriction (or ligation) sites described in Atlung cannot be considered recombination sites as that term is defined and used in the present specification and claims. Hence, the Examiner's assertion that ligation sites could be considered as "recombination sites" in accordance with the present invention remains incorrect.

In view of the foregoing remarks and under *Kalman*, Applicants respectfully assert that Atlung cannot and does not anticipate the claims as currently presented. Reconsideration and withdrawal of the rejection of claims 14-20, 27, 32, 33, 44-46 and 57 under 35 U.S.C. § 102(b) over Atlung therefore are respectfully requested.

IX. The Rejection of Claims 14-20, 27, 32-51 and 57 under 35 U.S.C. §§ 102 (a) or 102 (e) Over Hartley et al. is Traversed

The Examiner has also maintained the rejection of claims 14-20, 27, 32-51 and 57 under 35 U.S.C. §§ 102(a) or 102(e), for allegedly being anticipated by Hartley *et al.* (U.S. Patent No. 5,888,732); Doc. AF3, of record; hereinafter "Hartley"). *See* Office Action at pages 17-24, section 9. Applicants respectfully traverse this rejection.

The Examiner repeated the arguments set forth in the Office Action dated March 24, 2004, and further asserted that Applicants' arguments in the Reply dated June 23, 2004, were not persuasive. Specifically, the Examiner asserted that:

"integration sequence" is defined as "any nucleotide sequence that is capable of inserting randomly into a target nucleic acid molecule" (see the specification, page 22, last paragraph bridging to page 23, first paragraph). Since Hartley *et al.*, teach an Insert Donor DNA molecule comprising a desired DNA segment flanked by a first recombination site and a second recombination site and Hartley *et al.* disclose one or more integration sequences comprising at least one recombination site (ie., an insert Donor DNA molecule comprising a desired DNA segment flanked by a first recombination site and a second recombination site) as recited in claim 14. Furthermore, applicant does not provide an [sic] evidence to show why the Insert Donor DNA molecule comprising a desired DNA segment flanked by a first recombination site and a second recombination site taught by Hartley *et al.*, can not be inserted randomly into a target nucleic acid molecule. In fact, it is known that a DNA can be randomly inserted in the genome of a cell if the DNA is microinjected into the cell.

Office Action at pages 23-24. Applicants respectfully disagree with these assertions.

Applicants respectfully maintain that, for the reasons set forth in the previous Reply filed June 23, 2004, Hartley does not teach integration sequences as that term is defined and used in the present specification and claims. Specifically, as used in the present specification, ". . . an integration sequence is any nucleotide sequence that is *capable of inserting randomly* into a target nucleic acid molecule." Specification at pages 22-23 (emphasis added). Thus, the Insert Donor DNA flanked by recombination sites as described in Hartley inserts into a nucleic acid molecule at *specific* recombination sites, and therefore does not insert randomly.

Not only does Hartley not expressly describe integration sequences as that term is defined and used in the present specification and claims, the Examiner also has not shown that such integration sequences are inherently described in Hartley in order to meet the

burden of showing anticipation under 35 U.S.C. § 102(b). As with Atlung, the Examiner has merely made an unsupported assertion that "it is known that a DNA can be randomly inserted in the genome of a cell if the DNA is microinjected into the cell." Office Action at page 24. Again, Applicants respectfully submit that, for the same reasons discussed with respect to Atlung in the preceding section, this mere assumption is not only irrelevant, but also is not a sufficient basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic of random insertion necessarily flows from Hartley. In fact, even assuming, *arguendo*, that a DNA fragment microinjected into a cell *could* randomly insert into a genome, it is still an irrelevant point: Hartley says absolutely nothing about microinjecting the Insert Donor DNA into a cell. Moreover, the mere fact that a DNA fragment microinjected into a cell *can* randomly insert into the cell's genome does not guarantee that it *will* happen. It is at least equally likely that when a DNA molecule is microinjected into a cell that it is not incorporated into the host cell genome, particularly if the host cell is a bacterium, where it is more likely that the microinjected DNA remains extra-genomic. Thus, the Examiner has not shown how the concept of microinjection of a DNA fragment is established from Hartley, nor that random insertion of DNA into a genome necessarily flows from the act of microinjecting DNA into a host cell. Thus, Hartley does not teach the integration sequences as that term is defined and used in the present specification and claims.

The Examiner further asserted that "the rejected claims do not require at least one nucleic acid molecule or a nucleic acid segment comprising at least one integration sequence as suggested by applicant." Office Action at page 24. Applicants believe that the Examiner may have misunderstood Applicants' remarks at page 22 of the previous

Reply filed June 23, 2004. For clarification, the passage from page 22 of the previous reply has been reproduced below and modified to indicate the Applicants' intended meaning:

Independent claims 14 and 16 each are drawn to methods comprising, *inter alia*, inserting one or more integration sequences comprising at least one recombination site into at least one nucleic acid molecule. Independent claim 44 is drawn to a method comprising, *inter alia*, obtaining a first nucleic acid molecule comprising at least a first segment which comprises at least a first and a second recombination site, wherein said segment comprises at least one integration sequence. In contrast, Hartley does not disclose the insertion of one or more integration sequences into at least one nucleic acid molecule **[as in claim 14 or 16]** or a nucleic acid segment comprising at least one integration sequence **[as in claim 44]**.

Reply filed June 23, 2004 at page 22 (bracketed items inserted for clarification).

Applicants respectfully wish to make clear to the Examiner that the remarks excerpted above do not suggest, and were not intended to suggest, that any one of the present claims recites the phrase "at least one nucleic acid molecule or a nucleic acid segment comprising at least one integration sequence." Clearly, however, claim 14 recites "inserting one or more integration sequences comprising at least one recombination site into at least one nucleic acid molecule"; claim 16 recites "inserting one or more integration sequences, said one or more integration sequences comprising at least one recombination site, into at least one nucleic acid molecule"; and claim 44 recites "obtaining a first nucleic acid molecule comprising at least a first segment which comprises at least first and second recombination sites, wherein said segment comprises at least one integration sequence." As discussed in detail above, Hartley does not teach integration sequences as that term is defined and used in the present specification and claims. If applicants have misinterpreted what the Examiner meant by the statement "the

rejected claims do not require at least one nucleic acid molecule or a nucleic acid segment comprising at least one integration sequence as suggested by applicant," further clarification is respectfully requested.

In view of the foregoing remarks and under *Kalman*, Applicants respectfully assert that Hartley cannot and does not anticipate the claims as currently presented. Reconsideration and withdrawal of the rejection of claims 14-20, 32-51 and 57 under 35 U.S.C. §§ 102(a) or 102(e) over Hartley therefore are respectfully requested.

X. The Rejection of Claims 14-20, 27, 32-39, 44-51 and 57 under 35 U.S.C. § 102(f) is Traversed

The Examiner has maintained the rejection of claims 14-20, 27, 32-39, 44-51, and 57 under 35 U.S.C. § 102(f). Office Action at page 24, section 10. Applicants respectfully traverse this rejection.

In making this rejection, the Examiner contends that :

[Hartley et al.,] (US Patent No. 5,888,732) was filed on June 7, 1996 and published on March 30, 1999 and taught all limitations recited in claims 14, 16-20, and 30-43 [sic] (see above). However Gary Temple is not listed in [the] above patent, he can not [be] considered as [an] inventor of this instant application.

Id. Applicants respectfully disagree with the above-noted contentions.

As set forth in detail in the previous Reply filed June 23, 2004, and in the preceding section herein, Hartley does not disclose all of the elements of independent claims 14, 16 and/or 44 (and thus of the remaining claims that ultimately depend therefrom). In particular, Hartley fails to disclose the use of integration sequences. Contrary to the Examiner's assertions, the Insert Donor DNA molecule disclosed in Hartley cannot be considered an integration sequence as that term is defined and used in

the present specification. In any event, the invention claimed in Hartley is not identical to that claimed in present claims 14-20, 27, 32-39, 44-51 and 57. Accordingly, that Gary Temple is not named as an inventor in Hartley is irrelevant to the propriety of his being named as an inventor in the present application. The rejection under 35 U.S.C. § 102(f), therefore, is in error.

In view of the foregoing remarks, reconsideration and withdrawal of the rejection of claims 14-20, 27-39, 44-51 and 57 under 35 U.S.C. § 102(f) are respectfully requested.

XI. The Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting is Traversed

The Examiner has maintained the rejection of claims 14-20, 27, 32-39, 44-51 and 57 under the judicially created doctrine of obviousness-type double patenting over certain claims in Hartley. Office Action at pages 25-26, sections 11-12. Applicants respectfully traverse this rejection.

For the reasons discussed in the previous Reply filed June 23, 2004, and for the reasons discussed above distinguishing the presently claimed invention from the disclosure of Hartley, Applicants respectfully disagree with the Examiner's contention that the claims of the present invention are not patentably distinct from claims 27-39 of Hartley. Applicants therefore respectfully request that this rejection be reconsidered and withdrawn.

XII. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Date: Jan. 27, 2005

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